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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 09/539,748   | 03/31/2000  | Peter L. Rosenblatt  | PRC-006.01              | 9371             |
| 25181  | 7590        | 11/25/2003           | EXAMINER                |                  |
| FOLEY HOAG, LLP<br>PATENT GROUP, WORLD TRADE CENTER WEST<br>155 SEAPORT BLVD<br>BOSTON, MA 02110 |             |                      | ODLAND, KATHRYN P       |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 3743                    |                  |
|  |             |                      | DATE MAILED: 11/25/2003 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/539,748

Applicant(s)

ROSENBLATT ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-24, drawn to a system for soft tissue reconstructive surgery, classified in class 606, subclass 139.
  - II. Claims 25-36, drawn to a method for soft tissue reconstruction, classified in class 128, subclass 898.
  - III. Claims 37-38, drawn to a soft tissue fastener, classified in class 606, subclass 213.
  - IV. Claim 39, drawn to a method of surgical paravaginal repair, classified in class 128, subclass 834.
  - V. Claim 40, drawn to a method for diagnosing a pelvic floor defect, classified in class 128, subclass 830.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination requires

means for detaching which is not required of the combination. The subcombination has separate utility such as a fastener that does not require an applicator.

3. Inventions IV and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used for other applications than paravaginal repair, such as the bladder, rectum, etc.

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be used with another apparatus and vice versa. The method requires specifics such as stabilizing, driving and juxtaposition, which are not requirements of the apparatus.

5. Inventions I and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention the system for soft tissue reconstruction can be used for other applications than a pelvic floor and has separate utility such as for use in a bladder, rectum, etc. See MPEP § 806.05(d).

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6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group(s) (II, III, IV, and/or V), restriction for examination purposes as indicated is proper.

Further, if applicant selects any of Groups I-V, further election is required where applicable. For example, if applicant elects group V, a single template species must be elected.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

Fixation species

Species A: Figure 3

Species B: Figures 4A-4C

Species C: Figures 5A-5B

Species D: Figures 6A-6B

Species E: Figures 7A-7B

Species F: Figures 8A-8C

Species G: Figures 9A-9C

Species H: Figures 10A-10C

Species I: Figures 11A-11B

Species J: Figures 13A-13G

Species K: Figures 14A-14D

Species L: Figures 15A-15D

Species M: Figures 16A-16B

Species N: Figures 17A-17B

Species O: Figures 18A-18B

Species P: Figures 19A-19B

Species Q: Figures 20A-20D

Species R: Figures 21A-21I

Species S: Figures 22A-22C

Template species

Species 1: Figures 24A-24B

Species 2: Figures 25A-25E

Applicator species

Species A1: Figure 26

Species A2: Figures 27A-27C.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

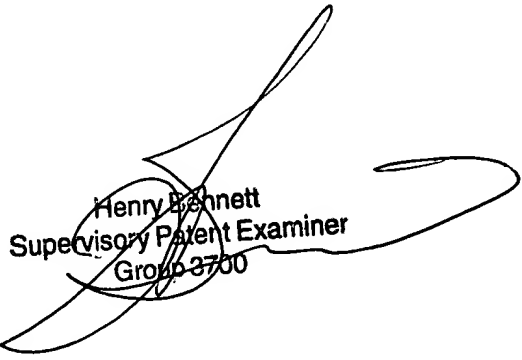
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO



Henry Bennett  
Supervisory Patent Examiner  
Group 3700